Exhibit 10

From: Herbert, Dellarese L <Dellarese.Herbert@fda.hhs.gov>
Sent: Tuesday, February 19, 2019 7:23 AM
To: Megha Shah; ORA PHARM1 RECALLS
Cc: Jeffrey Jackowski; Dan Burns; Jasleen Gupta; Global Complaints; Bushra Khan; US Pharmacovigilance
Subject: Nitrosamine Testing Discrepancies- AUROBINDO

Importance: High

Good morning Megha,

The agency found discrepancies with the nitrosamine testing for API and FDP. The agency would like Aurobindo to test both the API and FDP at the same time, using the same analyst/method/equipment to eliminate any testing variance and provide those results to the FDA as soon as possible.

Aurobindo Valsartan - NDEA

Lab	Drug	NDMA	NDEA
OTR	Valsartan API (DMF 24544)	N.D.	N.D.
OTR	Valsartan FDP	N.D.	N.D.-0.592
Aurobindo	Valsartan FDP	N.D.	N.D.-0.686

- API tested negative, but FDP tested positive for NDEA
- Aurobindo recalled 80 lots of FDP

Aurobindo Losartan FDP - NDMA

- Test results for Aurobindo losartan API and FDP

Lab	Firm	NDMA	NDEA
OTR	ZTP Losartan API (MF 028346)	N.D.	N.D.
OTR	Aurobindo API (MF 019671)	N.D.	N.D.
OTR	Aurobindo FDP	Up to 0.233	N.D.
Aurobindo	Aurobindo FDP	N.D.	N.D.

- Losartan FDPs

Drug Name	ANDA	DMF	Notes
Losartan Tablets	090083	019671	OTR testing shows FDP associated with Aurobindo's API
		028346	Appears that firm is claiming API from ZTP
Losartan/HCTZ Tablets	091629	019671	OTR testing shows FDP associated with Aurobindo's API
		028346	Appears that firm is claiming API from ZTP
		017728	DMF for HCTZ

Thanks, your response is appreciated.

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